

REMARKS

In the office action mailed June 10, 2005, claims 37-43 and 48-85 were pending. Claims 39-43, 53-55 and 57-85 were withdrawn from consideration, and claims 37-38, 48-51 and 56 stand rejected. In this response, claim 36 is amended, claims 57-85 are cancelled and claims 86-92 are added. Reconsideration of the present application as amended including claims 37-43, 48-56, and 86-92 in view of the remarks that follow is respectfully requested.

Claims 37, 38, 48-51 and 56 were rejected under 35 USC §102(b) as being anticipated by or, in the alternative, under 35 USC §103(a) as obvious over U.S. Patent No. 5,888,220 to Felt et al. Claim 37 has been amended in this response and recites that the instrument includes "a shaft extending between a proximal end and a distal end; and an inflatable portion adjacent said distal end, said inflatable portion having a reduced size configuration for insertion into the disc space and an enlarged inflated configuration, wherein when in said inflated configuration said inflatable portion defines an upper vertebral endplate contacting surface and an opposite lower vertebral endplate contacting surface, each of said upper and lower vertebral endplate contacting surfaces having a vertebral endplate contacting area no greater than 0.5 square inches."

The office action admits that Felt et al. does not "particularly disclose the upper and lower vertebral endplate contacting surfaces as each having an area in the range of 0.1 square inches to 0.5 square inches." The office action goes on to assert that the area would vary depending on the degree to which the balloon is inflated, and that at any given moment the balloon will comprise a vertebral endplate contact area in the range of 0.1 square inches to 0.5 square inches. While applicant does not acquiesce in whether or not the range of vertebral endplate contact areas is inherent in Felt et al., it is clear that Felt et al. does not disclose, either expressly or inherently, an inflatable portion where the vertebral endplate contact area is no greater than 0.5 square inches as recited in amended claim 37. Accordingly, Felt et al. cannot anticipate claim 37, and withdrawal of this basis of the rejection is respectfully requested.

It is also submitted that Felt et al. does not render claim 37 obvious. There is no teaching or suggestion in Felt et al. of limiting the vertebral endplate contact area of the

Response to First Office Action
Ser. No. 10/706,789
Atty Docket No. 4002-3449/PC466.02
Page 8 of 10

balloon to no greater than 0.5 square inches. A review of Felt et al. finds that it discloses employing a pressure of about 40 psi to about 60 psi in the balloon to distract a spinal disc space. See col. 5, lines 36-40. Accordingly, to apply a distraction load of 100 pounds, the vertebral endplate contact area of the Felt et al. balloon would have to be greater than 1.5 square inches even if the balloon is inflated to 60 psi. Amended claim 37 clarifies that the vertebral endplate contact area of the inflatable portion is no greater than 0.5 square inches when in the inflated configuration. If the vertebral endplate contact area in Felt et al. were so limited, distraction forces that could be applied could be insufficient. Accordingly, Felt et al. fails to teach or suggest claim 37, and withdrawal of this basis of the rejection is respectfully requested.

Claims depending from claim 37 were rejected and are allowable at least for the reasons claim 37 is allowable and for other reasons. For example, claim 56 recites "wherein in said inflated configuration said inflatable portion includes a spherical shape and circular vertebral endplate contacting surfaces on opposite sides thereof. " There is no disclosure, teaching or suggestion in Felt et al. of a balloon with a spherical shape. The only shapes specifically disclosed in Felt et al. appear to be the irregular shape shown in Fig. 1 and a cylindrical shape mentioned at col. 6, line 32. The office action asserts that col. 6, lines 6-20 of Felt et al. discloses the balloons can be provided in "any suitable form/shape, depending on the manner in which the biomaterial is delivered and cured." However, a review of this portion of the specification does not find any disclosure or suggestion of a geometrical shape of the balloon. Rather, this portion of the specification appears to be directed to forms of the balloon that are not shape related. For example, Felt et al. mentions balloon forms that have "a plurality of layers" and those with a "plurality of compartments" and also a "single, thin walled balloon" that can be left in situ between the annular material and the cured biomaterial. No disclosure or suggestion of a spherical shape is provided.

It is respectfully submitted that a prior art reference must suggest the desirability of a modification in order for the propose modification to render a claim obvious. Felt et al. does not disclose or suggest a spherical shape. It appears that the desirability of the modifications suggested in the Office Action is based on the teachings of applicant's

specification, which is not a proper reference. If this is not the case, then citation of a reference that teaches or suggests the desirability of modifying Felt et al. to provide a spherical balloon is respectfully requested. Alternatively, if the rejection is based on facts within the personal knowledge of the Examiner, then an affidavit providing the same is requested so the rejection can be considered and traversed if appropriate. Otherwise, withdrawal of the rejection of claim 56 depending from claim 37 is respectfully requested.

New claims 86-92 are readable on the elected species and also distinguish Felt et al. for the reasons provided above with respect to claim 56. Entry and allowance of new claims 86-92 is respectfully requested.

Reconsideration of the present application including claims 37-43, 48-56, and 86-92 in view of this response is respectfully requested. The examiner is encouraged to contact the undersigned to resolve any outstanding issues with respect to the present application.

Respectfully submitted

By: 

Douglas A. Collier
Reg. No. 43,556
Krieg DeVault LLP
One Indiana Square, Suite 2800
Indianapolis, Indiana 46204-2079
(317) 238-6333

Response to First Office Action
Ser. No. 10/706,789
Atty Docket No. 4002-3449/PC466.02
Page 10 of 10